SOPP 8503.2
Review of Import For Export Requests Under Section 801(d)(4) of the FD&C Act

APPENDIX 1

INFORMATION AND DOCUMENTATION THAT SHOULD BE SUBMITTED [U.S. FIRM AND FOREIGN MATERIAL SUPPLIER] PRIOR TO THE IMPORTATION OF BLOOD PRODUCTS FOR EXPORT:

	FOREIGN MATERIAL SUPPLIER	U.S. FIRM
Application submitted to CBER and approved under 801(d)(4)	Not Required, but permissible	Required
Registration and list or update registration and list	Required under section 510(i)(1) of the FD&C Act	Required
Description of safeguards which demonstrate assurances that U.S. licensed/approved products manufactured in the same facility will remain safe and effective for U.S. use (i.e., quarantine procedures for imported blood or blood components and final product from U.S. products, including validation data for cleaning procedures on shared equipment and facilities used for the production of both U.S. products and exported products).	Not Applicable	Required, for a firm that manufactures U.S. approved/license products for domestic commerce, only.
Description of how the product for export, which incorporates imported components, will not be diverted to domestic use in the U.S.	Not Applicable	Required
General donor screening questionnaire	Required	Not Applicable
Source material infectious disease testing	Required	Not Applicable
Pre-approval inspection	Not Applicable	Not Applicable
Routine inspection	Not Required, but possible due to section 704 of FD&C Act	Required
Subject to inspection	Not Required, but possible due to section 704 of FD&C Act	Required
Labels	Required	Not Applicable

NOTE: U.S. licensed facilities receiving non-blood components or non-blood products pursuant to section 801(d)(3) are required to report such changes in accordance with 21 CFR 601.12.

NOTE: Sections 801(d)(3) & (4) only apply to products/materials that are imported into the United States. Foreign manufacturers that have U.S. product or establishment licenses would not need to submit import for export requests, pursuant to 801(d)(4), for the products that are not imported into the U.S. The safeguards that demonstrate assurances that U.S. licensed products will remain safe and effective, should foreign manufacturers produce unlicensed products, would be described in their respective U.S. license applications.